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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/376,395Applicant(s)
Huang et alExaminer
Richard SchnizerGroup Art Unit
1632

Responsive to communication(s) filed on _____

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 46-136 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

☒ Claims 46-136 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 46-50, 52-54, 57-60, 62-71, 73, 77-80, 84-86, 89-92, 94-101, 103-105, 107-118, 122, 123, and 126-136, drawn to compositions comprising a polypeptide drug, and methods of making and using the compositions, classified in class 514, subclass 2.
- II. Claims 46-50, 52-54, 57-60, 62-71, 73, 77-80, 84-86, 89-92, 94-101, 103-105, 107-118, 122, 123, and 126-136, drawn to compositions comprising a polysaccharide drug, and methods of making and using the compositions, classified in class 514, subclass 23.
- III. Claims 46-50, 52-54, 57-60, 62-71, 73, 77-80, 84-86, 89-92, 94-101, 103-105, 107-118, 122, 123, and 126-136, drawn to compositions comprising an undefined non-polypeptide, non-polysaccharide, non-nucleic acid drug, and methods of making and using the compositions, classified in class 514, subclass 1.
- IV. Claims 46-136, drawn to therapeutic compositions comprising nucleic acids, and methods of making and using the compositions, classified in class 514, subclass 44.

Claims 46-50, 52-54, 57-60, 62-71, 73, 77-80, 84-86, 89-92, 94-101, 103-105, 107-118, 122, 123, and 126-136 are generic to a plurality of disclosed patentably distinct species. If a

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group containing any of these claims is elected, the generic claim or claims will be examined to the extent that it is defined by the classification of the elected group.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated because they comprise compositions which containing drugs with distinct structures and modes of action. It is noted that the species of drugs listed in groups I-III are not specifically disclosed in the claims. However, these species are disclosed in the specification at page 4, lines 14-26, and page 13, lines 13-19, thus the requirement to elect between these species is proper.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Election of Species

Claims 107, 108, 110, and 111 are generic to a plurality of disclosed patentably distinct species comprising targeting factors. Applicant is required under 35 U.S.C. 121 to elect a single species from the group consisting of modified lipids, proteins, polycations, receptor ligands, asialoglycoprotein, insulin, LDL, folate, monoclonal antibodies, and polyclonal antibodies, even though this requirement is traversed. Should applicant select modified lipids, proteins, polycations, receptor ligands, monoclonal antibodies, or polyclonal antibodies, a further election

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of a single, specific modified lipid, protein, polycation, receptor ligand, monoclonal antibody, or polyclonal antibody is required. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached on Mondays and Thursdays between the hours of 6:20 AM and 3:50 PM, and on Tuesdays, Wednesdays and Fridays between the hours of 7:00 AM and

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4:30 PM (Eastern time). The examiner is off every other Friday, but is usually in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. The FAX phone numbers for art unit 1632 are 703-308-4242 and 703-305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Richard Schnizer, Ph. D.

Karen M. Hauda
KAREN M. HAUDA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600